REMARKS

Claims 16-60 are currently pending. In an effort to facilitate prosecution of various methodology aspects of the present invention, Applicants have undertaken the following actions through this amendment: (a) the remaining system claims (claims 1-9 and 12-15) have been cancelled (without prejudice) such that claims 1-15 are no longer pending; (b) previously pending method claims 16-30 have been amended; and (c) new method claims 31-60 have been added. No new matter has been added. Applicants respectfully request reconsideration of the present application in light of the claim amendments and remarks below. Allowance of the claims is hereby earnestly solicited.

Claim Rejections

Claims 2-4 were rejected under 35 USC 112, 2nd paragraph, for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 2 and 3 have been amended to overcome this rejection, with claim 2 amended to include proper antecedent basis for the second usage of "dilating cannula" and claim 3 amended to positively recite the sequential dilating assembly. Applicants respectfully request that this rejection be withdrawn.

Claims 1-15 are no longer pending. As such, Applicants will address the rejections from the Office Action mailed April 19, 2007 as they relate to amended claims 16-30 and new claims 31-60.

Independent claim 16, as amended, recites a method of accessing a spinal target site via a lateral, trans-psoas surgical approach, comprising the steps of: (a) affixing a first retractor blade introduced to said spinal target site via a lateral, trans-psoas approach such that said first retractor blade is positioned along a posterior aspect of said spinal target site and fixed relative to said spinal target site; and (b) moving a second retractor blade introduced to said spinal target site via a lateral, trans-psoas approach relative to said affixed first retractor blade such that an operative corridor is established between said first and second retractor blades to said spinal target site.

New independent claim 31 recites a method of accessing a spinal target site via a lateral, trans-psoas surgical approach, comprising the steps of: (a) introducing a first retractor blade and a second retractor blade to said spinal target site via a lateral, trans-psoas surgical approach such that said first retractor blade is positioned along a posterior aspect of said spinal target site; (b) affixing said first retractor blade relative to said spinal target site through the use of an extension element extending from said first retractor blade into said spinal target site; and (c) moving said second retractor blade relative to said affixed first retractor blade such that an operative corridor is established between said first and second retractor blades to said spinal target site.

New independent claim 46 recites a method of accessing a spinal target site via a lateral, trans-psoas surgical approach, comprising the steps of: (a) introducing a first retractor blade to said spinal target site via a lateral, trans-psoas surgical approach such that said first retractor blade is positioned along a posterior aspect of said spinal target site; (b) affixing said first retractor blade relative to said spinal target site through the use of a first extension element extending from said first retractor blade into said spinal target site; (c) moving said second retractor blade relative to said affixed first retractor blade such that an operative corridor is established between said first and second retractor blades to said spinal target site; and (d) affixing said second retractor blade relative to said spinal target site through the use of a second extension element extending from said second retractor blade into said spinal target site.

Neither the Mayer or Slotman references (or any other prior art of record), whether taken alone or in combination, appear to contain any requisite teaching, suggestion or motivation that would have lead someone of ordinary skill in the art to the present invention now claimed in amended independent claim 16, new independent claim 31 and/or new independent claim 46. More specifically, there does not appear to be any teaching, suggestion, or motivation for a method of accessing a spinal target site via a lateral, trans-psoas surgical approach, wherein a first retractor blade is positioned and affixed along a posterior aspect of a spinal target site prior to having a second retractor blade moved relative to the affixed first retractor blade to establish an operative corridor to the spinal target site.

This is an important aspect of the present invention in that it allows an operative corridor to be safely established via a lateral, trans-psoas surgical approach to the spine. As detailed in the specification and drawings of the present application, Applicants are focusing on a lateral, trans-psoas surgical approach to the spine. The lateral surgical approach overcomes drawbacks with traditional anterior approach surgery, which requires the surgeon to establish an operative corridor through the abdomen of the patient. This necessarily requires delicate manipulation of the bowels to move them out of the way, as well great care to move or retract the various great blood vessels that traverse in front of the lumbar spine. The lateral surgical approach of the present invention also overcomes the drawbacks of traditional posterior surgery, which typically requires the reduction or removal of boney elements of the posterior region of the spine (e.g. spinous processes, transverse processes, etc...) in order to reach the intervertebral space. These drawbacks of prior art techniques are discussed on page 4, lines 11-20 of the specification.

A lateral approach avoids these challenges by establishing an operative corridor from the side of the patient (vs. the front of the patient during anterior surgery or the back of the patient during posterior surgery). The Applicants discovered that the optimal manner of establishing this corridor was to do so through the psoas muscle that flanks either side of the spine, particularly in the lumbar region (hence the "trans-psoas" claim limitation). This, it was found, avoided the neurological deficit experienced with the traditional manner of establishing lateral access the spine, which involved forcibly retracting the psoas muscle out of the way of the lateral aspect of the spine rather than traversing through it. The present invention as claimed is essential to a safe and reproducible trans-psoas approach in that it fixes the posterior retractor blade such that it cannot be moved posteriorly during the rest of the surgery. This is important because the exiting nerve roots are known to typically reside in the posterior one-third of the psoas muscle. The first retractor blade of the present invention is positioned along the posterior aspect of the spinal target site and then affixed in position with the exiting nerve roots "behind" (i.e. positioned posteriorly to) the first retractor blade. This can be seen clearly, for example, in Figs. 10-11, where the posterior retractor blade12 has been positioned along the posterior region of the disc space with the exiting nerve roots (shown as cylindrical structures disposed perpendicular to the longitudinal axis of the retractor blade 12) located in between the retractor blade 12 and the posterior elements of the vertebra. By fixing the first retractor blade in position along the posterior aspect of the spinal target site, any subsequent manipulation of the retractor (e.g. moving the second retractor blade relative to the first retractor blade to establish the operative corridor) will not cause the posterior retractor blade to move posteriorly and possibly impinge upon or otherwise compromise the exiting nerve roots that lie behind it. This can be seen, for example, with reference to Figs. 12-13 and the associated text at page 22, lines 13-24.

The cited references do not appear to teach and/or suggest these important features. The Mayer reference describes a retractor system for use in an anterior approach to the spine, as opposed to the lateral, trans-psoas approach as claimed (which overcomes the drawbacks of the anterior approach). This is evident with reference to Fig. 2 of Mayer, where only the anterior surface of the spine is illustrated, and even more so in Fig. 3 of Mayer, where the retractor blades only extend to the *anterior* surface of the spine. It is completely silent regarding a "first retractor blade positioned along a *posterior aspect* of the spinal target site" as claimed. Moreover, Mayer is also silent regarding any teaching of affixing a first retractor blade along a posterior aspect of the spinal target site *prior to moving a second retractor blade* relative to the first retractor blade to establish an operative corridor to the spinal target site.

The Slotman reference does not cure the deficiencies in Mayer. Slotman discloses an endoscopic spreader instrument with two arm members used primarily during anterior procedures. Slotman does not mention a lateral approach, much less the lateral, trans-psoas approach of the present invention whereby a first retractor blade is affixed along a posterior aspect of a spinal target site. Applicants respectfully assert that the arm members of Slotman do not constitute retractor blades of the present invention, as set forth in the claims. Even if, *arguendo*, one were to consider the arm members of Slotman as "retractor blades" (which Applicants do not believe or concede), these elements are not fixed to the spinal target site, much less in progressive order as in the present invention, with a first arm member affixed to the spinal target site prior to moving the second arm member relative to the first arm member to create an operative corridor to the spinal target site. Indeed, the arm members of Slotman are moved away from one another simultaneously. Nor does the spreader device of Slotman establish an "operative corridor to the spinal target site" as found in the present invention, but rather is introduced into a *pre-existing* operative corridor to the spinal target site (see Col. 7, lines 22-29).

The remaining references similarly do not appear to contain any teaching, suggestion or motivation regarding a "first retractor blade positioned along a *posterior aspect* of the spinal target site", as well as any teaching of affixing a first retractor blade along a posterior aspect of the spinal target site *prior to moving a second retractor blade* relative to the first retractor blade to establish an operative corridor to the spinal target site. For example, the Gharib reference disclose a tubular based retraction system which, by definition, does not have a first retractor blade nor a second retractor blade, much less a first retractor blade affixed along a posterior aspect of the spinal target site prior to moving a second retractor blade relative to the first retractor blade to establish an operative corridor to the spinal target site.

With such voids in the prior art, Applicants respectfully submit that claims 16, 31 and 46 would not have been obvious to one of ordinary skill in the art at the time of the invention such that this rejection should be withdrawn. Dependent claims 17-30, 32-45, and 47-60, being dependent upon and further limiting independent claims 16, 31, and 46, respectively, should be allowable for the reasons in support of the patentability of claim 16, 31 and 46, as well as the additional recitations they contain. Allowance of all currently pending claims (claims 16-60) is hereby earnestly solicited.

Conclusion

Favorable consideration and allowance of the claims are respectfully requested. In the event that there are any questions concerning this Response to Office Action or the application in general, the Examiner is cordially invited to telephone the undersigned attorney so that prosecution may be expedited. If there any fees or overpayments associated with this amendment or any accompanying paper, the Commissioner is authorized to debit or credit USPTO Deposit Account No. 50-2040.

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

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Date: October 19, 2007